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EXAMINER

COBANOGLU, DILEK B

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3626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/004,941	Applicant(s) DE LA HUERGA, CARLOS	
	Examiner DILEK B. COBANOGLU	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 193-217 and 219-222 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 193-217 and 219-222 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/02, 4/17/02, 2/19/03, 4/1/03, 5/28/03, 7/3/03, 9/4/03, 5/3/04, 11/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This communication is in response to the amendment received on 11/16/2007.

Claims 1-24, 193-217, 219-222 remain pending in this application.

Claim Objections

2. Claim objections for claims 199 and 219 have been withdrawn in light of renumbering and cancellation of some of the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, and 194-198, 200-201, 212, 213, 217, 219, 220-222 are rejected under 35 U.S.C. 102(b) as being unpatentable by Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,857,716).

A. Claim 1 has been amended now to recite a method for associating at least one medical device with a controller that is remote from the medical device, the method comprising the steps of:

- i. providing a device identifier that indicates a device network address of the medical device within a communication network (Gombrich; col. 2, lines 38-47, col. 3, lines 19-28, col. 9, lines 39-63, figure 10-12);

Examiner considers that "radio frequency bar code" as item (or device) identification information is same as a "network address" since in the specification Applicant describes "a pump identifier, which can be an RF address or frequency" in paragraph 0041.

- ii. providing a data collector (Gombrich; abstract, col. 9, line 64 to col. 10, line 15);
- iii. obtaining the device address via the data collector (Gombrich; col. 2, lines 18-21, col. 8, lines 31-39, col. 15, lines 9-16);
- iv. transferring the device address from the data collector to the controller (Gombrich; col. 4, lines 56-64, col. 15, lines 9-18); and
- v. associating the controller with the medical device so that the controller can communicate with the medical device (Gombrich; col. 2, lines 36-45).

B. Claim 194 has been amended now to recite the method of claim 1 further including the steps of:

- a. obtaining at least one of medication information from a medication container, patient information from a patient identification device and physician identification from a physician identification device (Gombrich; col. 2, lines 5-32, lines 52-56, col. 15, lines 9-18),
- b. the method further including performing at least two of the following identifying steps:

(i) identifying the time at which the address information is obtained (Gombrich; col. 2, lines 5-21, lines 38-47, col. 3, lines 21-30, col. 15, lines 9-16);

(ii) identifying the time at which the medication information is obtained from the medication container (Gombrich; col. 2, lines 5-21, lines 38-47, col. 3, lines 47-55).

(iii) Identifying the time at which the patient information is obtained from the patient identification device (Gombrich; col. 2, lines 5-21, lines 38-47, col. 3, lines 47-55, col. 15, lines 9-18).

Examiner considers that the time at which the identifying or scanning the identifier bar codes should be entered in the system since this information is sent to the computer system 42 (col. 15, lines 9-48) and “one of the embodiments of Gombrich reference of to monitor a nurse’s (or the medical professional’s) time with the patient and maintain a chronology of patient events such as when drugs are administered to the patient” (Gombrich’ col. 3, lines 49-55).

c. The method further including the step of comparing at least two of the identified times and when the duration between the compared times exceeds a threshold period, performing a health safety function (Gombrich; col. 15, line 9 to col. 16, line 2, col. 16, lines 28-50). Gombrich teaches in col. 15, lines 9-48 that the nurse will take bar code reading

device and read her identification bar code, then patient's identification bar bracelet, and then item identifier bar code on items (drugs) to be administered, and press "send" button when completed. Examiner considers that if the nurse does not press "send" button, the system would give error message, since the process would not be completed. And since "The computer system data files will include an adjustable time window adjusted and entered by the pharmacist in which the drug can be administered. If drug administration does not occur in this time window, the alert occurs."

C. Claim 195 has been amended now to recite the method of claim 194 wherein the identifying steps that may be performed in step (b) further include:

(iv) identifying the time at which the physician identification is obtained from the physician identification device (Gombrich; col. 15, lines 9-48); and

(v) identifying an authorize activation time indicating when a device has been authorize to deliver a medication to a patient (Gombrich; col. 15, lines 9-48);

the method further including performing at least a third of the identifying steps, the step of comparing including determining when the duration between the at least three identified times exceeds the threshold period, the health safety function performed when the duration between the

compared times exceeds the threshold period (Gombrich; col. 16, lines 28-50).

D. Claim 196 has been amended now to recite the method of claim 195 wherein the identifying steps that may be performed in step (b) further include:

(vi) Identifying a delivery activation time indicating when an activation command has been received to deliver a medication to a patient via the device (Gombrich; col. 15, lines 9-48, col. 16, lines 28-50); and

(vii) Identifying a verification time indicating when a medication verification process has been completed (Gombrich; col. 15, lines 9-48, col. 16, lines 28-50);

The method further including performing at least a fourth of the identifying steps, the step of comparing including determining when the duration between the at least four identified times exceeds the threshold period, the health safety function performed when the duration between the compared times exceeds the threshold period (Gombrich; col. 16, lines 28-50).

E. As per claim 197, Gombrich discloses the method of claim 194 wherein the each of the step of obtaining the medical device address and the step of obtaining at least one of the medication information the patient information and the physician information include readable label (Gombrich; col. 9, line 64 to col. 10, line 15).

F. As per claim 198, Gombrich discloses the method of claim 194 wherein the step of obtaining at least one of medication information from a medication container, patient information from a patient identification device and physician identification from a physician identification device includes obtaining the information using the data collector, the method further including transferring the obtained information to the controller (Gombrich; col. 9, line 64 to col. 10, line 21, col. 16, lines 3-17, col. 18, lines 43-60).

G. As per claim 199, Gombrich discloses the method of claim 198 wherein the step of identifying at least two times includes identifying the at least two times using the data collector, the method further including the step of transferring the at least two times to the controller (Gombrich; col. 15, line 9 to col. 16, line 2).

H. As per claim 200, Gombrich discloses the method of claim 194 wherein the step of performing a health safety function includes activating an indicator at one of the data collector, the medical device and the controller (Gombrich; col. 3, lines 1-6, col. 16, lines 28-50).

I. As per claim 201, Gombrich discloses the method of claim 1 further including the steps of obtaining patient identification information indicating a patient that is to be associated with the controller, associating the controller with the patient identification information, providing medication information on a medication container, obtaining the medication information from a medication container, using the medication information to determine specific patient information for whom the medication was dispensed, comparing the patient identification

information indicating the patient that is associated with the controller and the specific patient identification information and determining that the patient identification information indicating the patient that is associated with the controller is different than the specific patient identification information and activating an indicator (Gombrich; col. 2, lines 5-47, lines 52-56, col. 3, lines 21-30, col. 4, lines 56-64, col. 8, lines 31-55, col. 15, lines 9-48, col. 16, lines 28-50).

J. As per claim 212, Gombrich discloses the method of claim 1 including the steps of providing a medication container with a medication identifier containing medication information, using the data collector to obtain the medication information from the medication identifier, transmitting the medication information from the data collector to the controller and using the medication information to control the medical device (Gombrich; col. 2, lines 38-47, col. 3, lines 21-30, col. 4, lines 56-64, col. 15, lines 9-48).

K. As per claim 213, Gombrich discloses the method of claim 212 wherein the step of using the medication information to control the medical device includes the steps of the controller transferring the medication information to a medication database, using the medication information to identify medication control information in the database, providing the medication controller information to the controller and the controller using the medication control information to control the medical device (Gombrich; col. 4, lines 56-64, col. 15, lines 9-48).

L. As per claim 217, Gombrich discloses the method of claim 1 further including the step of associating the controller with a patient (Gombrich; col. 12, line 64 to col. 13, line 31).

M. As per claim 219, Gombrich discloses the method of claim 1 further including the steps of identifying at least two times when data obtaining events occur, comparing the data obtaining times and when the duration between data obtaining times for the events exceeds a threshold period, performing a health safety function (Gombrich; col. 15, lines 9-48, col. 16, lines 28-50).

N. As per claim 220, Gombrich discloses the method of claim 219 further including the step of obtaining at least one of medication information from a medication container, patient information from a patient identification device and physician identification from a physician identification device, the step of identifying at least two times including identifying:

- i. The time at which the address information is obtained (Gombrich; col. 15, lines 9-48);
- ii. The time at which the medication information is obtained from the medication container (Gombrich; col. 15, lines 9-48);
- iii. The time at which the patient information is obtained from the patient identification device (Gombrich; col. 15, lines 9-48).

O. As per newly added claim 221, Gombrich discloses the method of claim 194 wherein the step of performing a health safety function (Gombrich; col. 3, lines 1-6, col. 12, line 64 to col. 13, line 31).

P. As per newly added claim 222, Gombrich discloses the method of claim 194 wherein the identifying steps that may be performed in step (b) further include: identifying a prescribed time indicating the time prescribed for delivery of the medication to a patient (Gombrich; col. 13, lines 32-56, col. 14, lines 54-61, col. 16, lines 28-50).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-20, 22, 193, 202, 203, 208-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,857,716) in view of Examiner's official notice.

A. As per claim 2, Gombrich discloses the method of claim 1 wherein the obtaining step is via wireless communication (Gombrich; col. 15, lines 9-48).

- While Gombrich does not explicitly disclose that a wireless communication network is being used in transferring step, Official Notice is taken that wireless connections to various communication networks, such as telephone, television, and computer networks, are old and well known. Wireless communications between computers and medical devices all were well known and widely used within our society at the time of the present invention and have been

developed and used to allow the users more mobility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the terminals in Gombrich using known wireless technology. One would have been motivated to use wireless technology to connect the devices and a computer in order to allow the medical devices and the controller (or a remote computer) have a faster communication.

B. As per claim 3, Gombrich discloses the method of claim 2 further including the steps of, after associating, causing the controller to send a first communication to the device address and receiving the first communication at the medical device (Gombrich; col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

C. As per claim 4, Gombrich discloses the method of claim 3 wherein the step of sending the first communication includes the step of transmitting a controller address of the controller within the communication network (Gombrich; col. 15, lines 9-48).

D. As per claim 5, Gombrich discloses the method of claim 3 further including the step of, in response to the first communication, causing the medical device to perform a safety function (Gombrich; col. 15, lines 49 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

E. As per claim 6, Gombrich discloses the method of claim 5 wherein the medical device includes an indicator and the safety function includes activating the indicator (Gombrich; col. 15, lines 49 to col. 16, line 2).

F. As per claim 7, Gombrich discloses the method of claim 5 wherein the medical device includes a transmitter and the safety function includes causing the medical device to transmit a second communication responsive to the first communication (Gombrich; col. 15, lines 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

G. As per claim 8, Gombrich discloses the method of claim 7 wherein the second communication includes the status of the medical device (Gombrich; col. 15, lines 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

H. As per claim 9, Gombrich discloses the method of claim 7 wherein the second communication is transmitted to the controller (Gombrich; col. 15, lines 9 to col. 16, line 2, col. 16, lines 28-50).

I. As per claim 10, Gombrich discloses the method of claim 5 further including the steps of storing a first patient information set in the medical device indicating information related to a patient for which the medical device has been provided and storing a second patient information set in the controller indicating information related to a patient and wherein the step of causing the controller to send a first communication includes the step of transmitting the second patient information set to the device address, the step of receiving includes receiving the first patient information subset at the medical device and wherein the step of causing the device to perform a first safety function includes comparing the first and second patient information sets (Gombrich; col. 8, line 31 to col. 9, line 7, col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

J. As per claim 11, Gombrich discloses the method of claim 10 further including the step of providing an indicator on the medical device and wherein the step of causing the device to perform the safety function further includes the step of,

when the first and second patient information sets are different, activating the indicator (Gombrich; col. 15, line 9 to col. 16, line 2).

K. As per claim 12, Gombrich discloses the method of claim 10 wherein the step of storing the first patient information set on the medical device includes the step of storing the first patient information set on an information device, the information device being one of a medication delivery container, a patient mounted device and a physician's computing device, establishing a communication link between the information device and the medical device and transferring the first patient information set from the information device to the medical device (Gombrich; col. 2, lines 5-32, lines 38-47).

L. As per claim 13, Gombrich discloses the method of claim 12 wherein the information device is an IV bag (Gombrich; col. 2, lines 38-47).

M. As per claim 14, Gombrich discloses the method of claim 10 wherein the step of storing the first patient information set on the medical device includes the step of providing a medical device interface and entering the first patient information set via the interface device (Gombrich; col. 12, line 64 to col. 13, line 31).

N. As per claim 15, Gombrich discloses the method of claim 10 wherein each of the medical device and the controller are system devices, the method further includes the step of providing at least a third system device and wherein the step of storing the second patient information set on the controller includes the step of storing the second patient information set on the third system device, establishing a communication link between the third system device and the

controller and transferring the second patient information set from the third system device to the controller (Gombrich; col. 12, line 64 to col. 13, line 31, col. 15, lines 9-48).

O. As per claim 16, Gombrich discloses the method of claim 15 wherein the step of providing the third system device includes the step of providing a patient mounted device (Gombrich; col. 12, line 64 to col. 13).

P. As per claim 17, Gombrich discloses the method of claim 16 wherein the step of providing a patient mounted device includes providing a wrist band (Gombrich; col. 12, line 64 to col. 13).

Q. As per claim 18, Gombrich discloses the method of claim 10 wherein the step of storing the second patient information set on the controller includes the step of providing a controller interface and entering the second patient information set via the interface device (Gombrich; col. 8, lines 31-55).

R. As per claim 19, Gombrich discloses the method of claim 7 further including the steps of storing a first patient information set in the medical device indicating information related to a patient for which the medical device has been provided and storing a second patient information set in the controller indicating information related to a patient and wherein the step of causing the device to perform a safety function includes the steps of transferring a second communication to the controller including the first patient information set and comparing the first and second patient information sets (Gombrich; col. 15, line 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

S. As per claim 20, Gombrich discloses the method of claim 19 further including the step of providing an indicator on the medical device and wherein the step of causing the device to perform the safety function further includes the step of, when the first and second patient information sets are different, activating the indicator (Gombrich; col. 15, line 9 to col. 16, line 2).

T. As per claim 22, Gombrich discloses the method of claim 2 further including the steps of, after associating, causing the controller and medical device to perform a health safety function (Gombrich; col. 15, line 9 to col. 16, line 2).

U. As per claim 193, Gombrich discloses the method of claim 1, wherein the obtaining step includes reading a bar code on the medical device and the transferring step includes transferring the device address (Gombrich; col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

V. As per claim 202, Gombrich discloses the method of claim 3 further including the step of using the medical device address to send the first communication (Gombrich; col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

W. As per claim 203, Gombrich discloses the method of claim 2 further including the steps of, after the step of associating the one medical device with the controller, communicating wherein the medical device transmits information to the controller (Gombrich; col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

X. As per claim 208, Gombrich discloses the method of claim 2 wherein the medical device is a first medical device and the device address is a first medical device address, the method further including the steps of providing a patient identifier that includes patient identifying information, using the data collector to obtain the patient identifying information from the patient identifier and transmitting the patient identifying information to the controller (Gombrich; col. 2, lines 5-32, col. 15, lines 9-48).

Y. As per claim 209, Gombrich discloses the method of claim 208 further including the steps of providing at least a first medication container that includes medication information associated with a medication in the first medication container, the medication information including specific patient information indicating the patient for whom medication in the container is prescribed, obtaining at least a subset of the medication information from the first medication container using the data collector and transmitting the at least a subset of the medication information to the controller (Gombrich; col. 2, lines 5-32, col. 15, lines 9-48).

Z. As per claim 210, Gombrich discloses the method of claim 209 further including the steps of using the medication information transmitted to the controller to identify specific patient information indicating the patient for whom the medication in the first medication container has been prescribed, comparing the patient identifying information from the patient identifier and the specific patient information and when the compared information is different, activating an indicator (Gombrich; col. 15, lines 9-48).

AA. As per claim 211, Gombrich discloses the method of claim 210 wherein the step of using the medication information transmitted to the controller to identify specific patient information includes the step of transferring the medication information from the controller to a remote computer and locating the specific patient identification information by the remote computer in a medication database (Gombrich; col. 15, lines 9-48).

Art Unit: 3626

7. Claims 21, 23, 24, 207, 214, 215, 216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,835,372) in view of Kerns et al. (hereinafter Kerns) (U.S. Patent No. 4,756,706).

A. As per claim 21, Gombrich discloses the method of claim 1.

- Gombrich fails to expressly teach an infusion pump, per se, since it appears that Gombrich is more directed to special medications, tests, IV's, etc. (Gombrich; col. 9, lines 39-47). However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses a plurality of infusion pumps (Kerns; abstract, col. 2, lines 49-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of remotely monitoring an infusion pump as well as other medical devices.

B. As per claim 23, Gombrich discloses the method of claim 22 further including the steps of storing a first patient information set in the medical device indicating information related to a patient for which the medical device has been provided and storing a second patient information set in the controller indicating information related to a patient, the medical device and controller each being system devices and the first and second patient information sets each being identifying information sets and, wherein, the step of performing a health safety function further includes the steps of causing a first of the system devices to

transmit a first of the identifying information sets to a second of the system devices, receiving the first identifying information set at the second system device and comparing the first and second identifying information sets (Gombrich; col. 12, line 64 to col. 13, line 31, col. 15, lines 9-48).

C. As per claim 24, Gombrich discloses the method of claim 23 further including the step of providing an indicator linkable to the second of the system devices and wherein the step of performing a health safety function further includes the step of, where the first and second identifying sets are different, activating the indicator (Gombrich; col. 15, line 9 to col. 16, line 2).

D. As per claim 206, Gombrich discloses the method of claim 1.

- Gombrich fails to expressly teach an infusion pump, per se, since it appears that Gombrich is more directed to special medications, tests, IV's, etc. (Gombrich; col. 9, lines 39-47). However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses a plurality of infusion pumps (Kerns; abstract, col. 2, lines 49-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of remotely monitoring an infusion pump as well as other medical devices.

- Gombrich fails to expressly teach transmitting a signal from the infusion pump to the controller indicating that the infusion pump is

no longer operative and, when the signal is received at the controller disassociating the controller from the infusion pump. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses transmitting a signal from the infusion pump to the controller indicating that the infusion pump is no longer operative and, when the signal is received at the controller disassociating the controller from the infusion pump (Kerns; abstract, col. 4, lines 43-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of increasing safety.

E. As per claim 207, Gombrich discloses the method of claim 206.

- Gombrich fails to expressly teach prior to transmitting the signal from the infusion pump to the controller indicating that the infusion pump is no longer operative, determining that a infusion pump line is no longer connected to the infusion pump, the step of transmitting the signal from the infusion pump including transmitting the signal when the line is disconnected from the infusion pump. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses prior to transmitting the signal from the infusion pump to the controller indicating that the infusion pump is no longer operative, determining that a infusion pump line is no longer connected to the infusion pump, the step of transmitting the signal from the infusion pump including transmitting the signal when the line is disconnected from the infusion pump (Kerns; abstract, col. 4, lines 43-50, col. 6, line 63 to col. 7, line 10, col. 9, line 60 to col. 10, line 8).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of increasing safety.

F. As per claim 214, Gombrich discloses the method of 1, wherein the device address is a first device address associated with the first pump assembly (Gombrich; col. 9, lines 39-47, col. 16, lines 18-57)

- The obviousness of modifying the teaching of Gombrich to include an infusion pump (as rejected by Kerns) is as addressed above in the rejection of claim 21 and incorporated herein.
- Gombrich fails to expressly teach at least first and second pump assemblies and providing a second device address for the second pump assembly, obtaining the second device address using the data collector, transmitting the second device address to the controller and the controller monitoring operation of the first and

second pump assemblies. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses at least first and second pump assemblies and providing a second device address for the second pump assembly, obtaining the second device address using the data collector, transmitting the second device address to the controller and the controller monitoring operation of the first and second pump assemblies (Kerns; abstract, col. 2, lines 49-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of providing a versatile tool for the central management of multiple intravenous infusions (Kerns; col. 7, lines 36-45).

G. As per claim 215, Gombrich discloses the method of claim 214 further including the steps of obtaining with the data collector first and second medication information from first and second medication labels associated with first and second infusion bags containing first and second medications and transferring the first and second medication information to the controller and determining that the first and second medications can be used together (Gombrich; col. 15, lines 9-48).

H. As per claim 216, Gombrich discloses the method of claim 215 wherein the step of determining that the first and second medications can be used together

includes determining they are for the same patient (Gombrich; col. 15, lines 9-48).

8. Claim 201 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,835,372) in view of Vasko (U.S. Patent No. 5,871,465).

A. As per claim 201, Gombrich discloses the method of claim 194 wherein the step of performing a health safety function includes one of the data collector and the controller transmitting a signal to the medical device to disable the medical device.

- Gombrich fails to expressly teach the controller transmitting a signal to the medical device to disable the medical device. However, this feature is well known in the art, as evidenced by Vasko.

In particular, Vasko discloses the controller transmitting a signal to the medical device to disable the medical device (Vasko; col. 4, lines 24-40, col. 7, line 64 to col. 8, line 8).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Vasko with the motivation of increasing the safety.

9. Claim 204 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,835,372), Examiner's Official Notice and further in view of Engleson et al. (hereinafter Engleson) (U.S. Patent No. 5,781,442).

A. As per claim 204, Gombrich discloses the method of claim 203. Claim 204 further including the steps of providing at least a second medical device that is not associated with the controller wherein when any medical device transmits information that is received by the controller, the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller.

- Gombrich fails to expressly teach a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller. However, this feature is well known in the art, as evidenced by Engleson.

In particular, Engleson discloses a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller (Engleson; abstract, col. 2, lines 53-66, figure 2). Examiner considers that since Engleson teaches plural of infusion pumps and further identifying and verifying correct medication for the patient,

therefore Engleson is matching the pumps with a controller or a controlling computer for identification and verification purposes and ignores other information received from other devices that do not match.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Engleson with the motivation of increasing the safety and security.

10. Claim 205 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,835,372), Examiner's Official Notice, Engleson et al. (hereinafter Engleson) (U.S. Patent No. 5,781,442) and further in view of Kerns et al. (hereinafter Kerns) (U.S. Patent No. 4,756,706).

A. As per claim 205, Gombrich discloses the method of claim 2 wherein the medical device is a first medical device and the first medical device address is a first medical device address the method further including the steps of providing a first indicator that is associated with the first medical device (Gombrich; col. 9, lines 39-47, lines 64-66).

- Gombrich fails to expressly teach a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller.

However, this feature is well known in the art, as evidenced by Engleson.

In particular, Engleson discloses providing a second medical device with a second device address and a second indicator, obtaining the second device address via the data collector; transferring the second device address from the data collector to the controller and associating the controller with the second medical device so that the controller can communicate with the second medical device (Engleson; abstract, col. 2, line 39 to col. 3, line 5).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Engleson with the motivation of increasing the safety and security.

- Gombrich fails to expressly teach using the controller to select information related to the first medical device and using the first medical device address to send a signal to the first medical device, receiving the signal by the first medical device and using the signal to activate the first indicator. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses using the controller to select information related to the first medical device and using the first

medical device address to send a signal to the first medical device, receiving the signal by the first medical device and using the signal to activate the first indicator (Kerns; abstract, col. 2, lines 49-55, col. 7, line 50 to col. 8, line 3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of increasing the safety and security.

Response to Arguments

11. Applicant's arguments with respect to claims 1-24, 193-217, 219-220 have been considered but are moot in view of the new ground(s) of rejection.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 3626

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626

/Robert Morgan/
Primary Examiner, Art Unit 3626